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IN THE
Supreme Court of the United States

J.E.M. AG SUPPLY, INC. (d/b/a Farm Advantage, Inc.), FARM ADVANTAGE, INC., LARRY BENZ, MERLE PRUETT (d/b/a Siouxland Seeds, Inc.), KEVIN WOLFSWINKEL, TIM KAMSTRA, AND TOM EISCHEN SEED & CHEMICALS,

Petitioners,

v.

PIONEER HI-BRED INTERNATIONAL, INC.,

Respondent.

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

BRIEF *AMICUS CURIAE* OF THE BIOTECHNOLOGY INDUSTRY ORGANIZATION IN SUPPORT OF RESPONDENT SEEKING AFFIRMANCE

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QUESTION PRESENTED

Whether plants developed by human intervention are statutory subject matter for utility patents under 35 U.S.C. § 101 *et seq.*?

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BRIEF *AMICUS CURIAE*

Pursuant to Supreme Court Rule 37.3(a), on written consent of all parties filed with the Court concurrently with this submission, the Biotechnology Industry Organization ("BIO") respectfully submits this brief *amicus curiae* in support of Respondent.[1]

INTERESTS OF THE *AMICUS CURIAE*

Amicus curiae, the Biotechnology Industry Organization, is a trade association consisting of over 900 companies, academic institutions, and biotechnology centers.[2] BIO members file thousands of patent applications each year for inventions ranging from fundamental technological breakthroughs to important commercial refinements of existing technology. Thus, BIO is concerned with the proper and consistent interpretation of the scope of patentable subject matter for utility patents, 35 U.S.C. § 101.

The biotechnology industry in the United States has the potential to radically increase current levels of agricultural production, dramatically improve the quality of health care, and measurably contribute to a cleaner environment. Agricultural biotechnology, for example, promises to

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[1] Pursuant to Rule 37.6, *amicus curiae* states that no person or entity other than BIO, its members (excluding Respondent Pioneer), or its counsel has made any monetary contribution to the preparation or submission of this brief. Further, no counsel for Petitioner or Respondent authored this brief in whole or in part.

[2] BIO advises the Court that Respondent Pioneer Hi-Bred International, Inc. is a member of the association. However, Respondent was excluded from all BIO deliberations and discussions regarding this *amicus* brief.

improve food production by enhancing crops' resistance to natural enemies and harsh environmental conditions, thereby lessening reliance on pesticides and other crop inputs, reducing farmers' costs (including fuel costs), and controlling soil erosion and compaction. In addition, the biotechnology industry makes substantial contributions to the U.S. economy—in 1999, for example, the industry as a whole invested some $9.9 billion in research and development, and the agricultural biotechnology sector alone generated $2.3 billion in revenues.

BIO members both hold and continue to apply for patents on inventions embodied in a wide range of seeds and seed-grown plants. The Patent and Trademark Office has been granting such patents without any suggestion of doubt for over 15 years. In response to decisions of this Court and the Courts of Appeals, BIO members have relied on the availability of utility patent protection for plant inventions to plan and make significant commercial investments, to direct their research and development activities, and to launch and develop products and product lines. Like other innovation-based U.S. industries, BIO members depend on the availability, as confirmed by the courts and the PTO, of utility patents. BIO thus endorses the holding of the U.S. Court of Appeals for the Federal Circuit that inventions embodied in seeds and seed-grown plants are patentable subject matter under 35 U.S.C. § 101.

BIO members also protect intellectual property they develop that is embodied in plant varieties—especially advances that do not rise to the standards required for utility patents—using the more limited rights conferred by the Plant Patent Act ("PPA"), 35 U.S.C. § 161 *et seq.*, and the Plant Variety Protection Act ("PVPA"), 7 U.S.C. § 2321 *et seq*. Because the PPA and the PVPA protect different aspects of BIO members' agricultural innovations than do utility patents, BIO has a strong interest in ensuring that the

statutes are interpreted in a manner consistent with the role the more limited forms of intellectual property play *vis-à-vis* utility patents.

Because BIO members' innovations span the whole spectrum of inventive activity, BIO can provide the Court with a broad perspective on the need for intellectual property protection, and on how different kinds of intellectual property protection can interact and overlap without conflict.

Accordingly, BIO files this brief in support of Respondent recommending affirmance of the decision of the U.S. Court of Appeals for the Federal Circuit, which held that seeds and seed-grown plants constitute patentable subject matter under 35 U.S.C. § 101.

SUMMARY OF THE ARGUMENT

The only constant in the "useful Arts," U.S. Const. art. I § 8, cl. 8, is change. Technology can now produce products and processes that the Founders, or even Congresses only decades ago, could never have imagined. Plants, which were once thought of as produced solely through forces of nature (and therefore not patentable), are now recognized as objects capable of being produced through the specific and directed efforts of individuals.

Because Congress understood that new and unforeseeable types of inventions—like inventions embodied in plants—would emerge from the inventive efforts of our citizens, it crafted a broad and flexible utility patent statute. Now that agricultural biotechnology has progressed to the point that it can yield advances that pass the tests of novelty, usefulness, non-obviousness, and full disclosure, 35 U.S.C. §§ 101-103, 112, its inventions merit the broader scope of utility patent protection.

Congress also decided to confer lesser forms of protection for plant-related innovations that do not meet the high standards required for a utility patent. Indeed, at the time the Plant Patent Act ("PPA") was passed in 1930, it was probably unimaginable that any new plant produced through conventional plant breeding techniques could ever meet the requirements for utility patents (*i.e.* that the plant be new, non-obvious, and useful, and, in particular, susceptible of full description). The PPA, like the Plant Variety Protection Act ("PVPA") that followed some 40 years later, gives those who discover or produce hybrids or plant varieties by fairly obvious and well-known procedures only limited exclusive rights for their efforts.

As the Patent and Trademark Office ("PTO") and the U.S. Court of Appeals for the Federal Circuit have recognized, there is nothing inconsistent about these parallel statutory schemes, which protect different subject matter (*i.e.* inventions embodied in plants on the one hand, and new plant varieties on the other) by conferring different exclusive rights based on different tests for eligibility. This remains true even though it is possible for the different innovations to manifest themselves in the same plant.

Moreover, if Congress were in any way concerned about overlapping forms of intellectual property rights in plants, it had ample opportunities to express that concern through "corrective" legislation in the more than 15 years that the PTO has granted utility patents for plant inventions. Indeed, rather than acting to correct the practice of the PTO, Congress has given every indication that it is aware of, and pleased with, the full panoply of rights available to those who develop plant inventions and new plant varieties. Accordingly, this Court should affirm the holding of the Federal Circuit that the utility patent statute means exactly what it says: "[w]hoever invents . . . any new and useful . . .

manufacture[3] . . . may obtain a patent therefor." 35 U.S.C. § 101.

ARGUMENT

I. Utility Patents, § 161 Plant Patents, and Plant Variety Protection ("PVP") Certificates Are Distinct Forms of Protection for Different Types and Degrees of Innovation.

Agricultural science has changed radically since Congress first established the modern patent system. Plant breeding progressed in the 1920s to the point that new varieties could be bred, identified, and replicated—in other words, to the point that plants developed by breeding efforts deserved some measure of intellectual property protection, even if their products (new varieties) or processes of production (breeding) were not sufficiently "inventive" to merit utility patent protection. More recently, plant biotechnology has crossed the utility patent threshold. Scientific advances dating from the late 1970s have enabled inventors to produce new, useful, non-obvious and readily reproducible plants through directed and specific genetic modifications. Today, inventors are able to combine detailed, gene-by-gene knowledge of plant genomics with molecular marker technologies to guide their breeding to produce new and improved plant varieties that are not transgenic, but would never occur in nature.

Our intellectual property laws have accommodated these developments: Congress has provided three distinct yet compatible forms of intellectual property protection for these different types and degrees of innovative activity,

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[3] Plant inventions may fall into one or more statutory categories of invention (*i.e.* manufactures or compositions of matter). For simplicity, BIO focuses in this brief on plants that are "manufactures."

namely (1) utility patents under 35 U.S.C. § 101 *et seq.*, for inventions embodied in plants; (2) so-called "plant patents" under the PPA, 35 U.S.C. § 161 *et seq.* (hereinafter "§ 161 plant patents") for asexually reproduced plant varieties; and (3) plant variety protection ("PVP") certificates under the PVPA, 7 U.S.C. § 2321 *et seq.*, for sexually reproduced plant varieties. These distinct legal instruments protect different subject matter—even though that subject matter may coexist in the same plant in the farmer's field—using different eligibility tests, and they confer different rights on their owners.

A. Intellectual Property Rights for Plant Innovations Have Evolved in Tandem with Scientific Advances.

Our patent system, which dates almost to the founding of the Republic, saw its first heyday during the Industrial Revolution. While George Washington in his first annual address to Congress noted that "[t]he advancement of agriculture, commerce, and manufactures by all proper means will not, I trust, need recommendation,"[4] little attention was paid to applying the patent system to plant-related innovations until the early 20th century. *See generally* Cary Fowler, *The Plant Patent Act of 1930: A Sociological History of its Creation*, 82 J. Pat. & Trademark Off. Soc'y 621, 631 (2000).

At the time Congress was considering the Plant Patent Act of 1930, most doubted that a new plant could ever meet all the statutory requirements for patentability (*e.g.*, that a new plant could be described with particularity). *See id.* at 641-42. There was also a general perception that plant

[4] George Washington, First Annual Message to Congress (Jan. 8, 1790), *reprinted in* The Papers of George Washington 543, 545 (W.W. Abbott & Dorothy Twohig, eds. 1987).

breeding was simply not an "inventive" activity. For example, particular strains of ornamental flowers or fruit trees, such as the "Delicious" apple, were more often the result of a grower's chance discovery than of any purposeful development. *See id.* at 640-41. Additionally, plants were perceived by many to be products of nature, outside the scope of patentable subject matter under R.S. § 4886, the forerunner of today's 35 U.S.C. § 101.

More pragmatically, utility patent eligibility requirements were thought to present an insurmountable barrier for plant varieties. A patent application must describe the "invention" with sufficient particularity to enable someone skilled in the relevant technological field to make and use the claimed invention without undue experimentation. *See* 35 U.S.C. § 112. For new plant varieties, the would-be practitioner in 1930 would have needed direct access to the original grower's biological stock—no amount of verbal or textual description could provide instructions that would, with a reasonable degree of experimentation, enable another to "recreate" a plant identical to the variety that the grower made through his plant breeding efforts.

Nevertheless, as the nursery industry became a commercial enterprise of national scope, plant propagators' and breeders' need for some form of intellectual property protection for their efforts grew. *See* Fowler at 630-31. In response, Congress enacted the PPA in 1930, creating a new legal instrument, the plant patent, to protect the output of plant breeding efforts. PPA, *now codified at* 35 U.S.C. § 161 *et seq.* The requirements for and attributes of a § 161 plant patent are purposefully stated in different terms than those used to define requirements for and characteristics of utility patents. Whereas an invention under 35 U.S.C. § 101 must be "new and useful" (and meet the criteria of §§ 102-03, and § 112 as well) to obtain utility patent protection, a

plant variety need only be "distinct and new" to be protected by a plant patent, 35 U.S.C. § 161. Moreover, § 161 plant patent applications are expressly exempt from the description requirements of 35 U.S.C. § 112 so long as "the description is as complete as is reasonably possible." 35 U.S.C. § 162.

Only asexually (vegetatively) propagated plants were made eligible for PPA protection; the PPA expressly excludes tuber-propagated plants as well as "plant[s] found in an uncultivated state." 35 U.S.C. § 161. The restricted scope of the Act again reflected the scientific understanding of the times: in 1930 there was no consensus over whether sexually (seed) propagated plants and tubers could in fact be distinguished from naturally occurring plants. *See* Fowler at 641. Congress hoped to avoid that pitfall by limiting PPA protection to asexually propagated plant varieties—such as those produced by grafting a part of one plant variety onto another. *See id.*

By 1970, conventional beliefs had shifted and scientific understanding of plant biology had again advanced. Concerns and doubts as to our ability to distinguish new sexually propagated plant varieties from their naturally occurring predecessors had abated. That year, Congress extended non-patent protection to seed-propagated plants by enacting the Plant Variety Protection Act ("PVPA"), codified at 7 U.S.C. § 2321 *et seq.*

Like the PPA, the PVPA offers limited protection for the output of plant breeding efforts—new plant varieties—that typically fall short of the standards required for utility patents. The basic requirement for obtaining a Plant Variety Protection ("PVP") certificate is similar to that for securing a § 161 plant patent: the plant variety must be new, distinct, uniform, and stable. 7 U.S.C. § 2402. Similarly, an application for a certificate must generally provide a description that is "adequate or as complete as is reasonably

possible," 7 U.S.C. § 2422, but it need not provide the degree and detail of disclosure needed to enable a third party to recreate the new plant variety, as is required of utility patent specifications under 35 U.S.C. § 112.

Throughout the latter half of the 20th century, our understanding of plant biology and plant development technology also developed in another direction: biotechnology. As a result of progress in the scientific fields that propel biotechnology (*e.g.*, molecular genetics, molecular biology, plant physiology), scientists learned how to specifically and precisely manipulate a plant's genome, either to over- or under-express specific plant genes, or to express exogenous genes (*i.e.* genes not found in the natural genome of the plant) that are intentionally inserted into the plant's genetic makeup. This kind of specific, reproducible, and focused inventive activity can meet all the threshold criteria for utility patents—novelty, usefulness, and non-obviousness, 35 U.S.C. §§ 101-103. Most importantly, these types of plant inventions can be fully and precisely described (using a procedural device, the deposit of a sample, that itself developed over the second half of the century[5]) in a way that enables a third party to reproduce the invention without undue experimentation, thereby satisfying the requirements of 35 U.S.C. § 112.

Thus, utility patents have come to be available for plants—more specifically, for biotechnology inventions

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[5] This device was originally developed for microbiological inventions, but has been adopted for plants: samples of seeds or plant cell tissue cultures are made freely available to the public upon the grant of the patent. *See In re Argoudelis*, 434 F.2d 1390 (C.C.P.A. 1970); *see also* 37 C.F.R. §§ 1.801-09. These "descriptions" allow someone practiced in the field to grow a genetic duplicate of any deposited plant described in a utility patent.

embodied in plants. The PTO relied on the authority that Congress had already provided in the adaptable and broadly worded utility patent statute to issue the first plant-related utility patents in 1975,[6] and to begin issuing them on a more regular basis in 1985. And because "[p]atentability shall not be negatived by the manner in which the invention was made," 35 U.S.C. § 103(a), utility patents are available not only for inventions involving recombinant genetic manipulation of plants, but for all plant inventions that meet the statutory criteria of novelty, usefulness, and non-obviousness.

B. Utility Patents, § 161 Plant Patents, and PVP Certificates Protect Different Types and Degrees of Inventiveness and Provide Different Forms of Intellectual Property Rights.

Consistent with the different eligibility standards for securing a utility patent, a § 161 plant patent, or a PVP certificate, the three instruments confer different exclusive rights on the successful applicant. A § 161 plant patent or a PVP certificate grants rights that are defined exclusively in terms of the protected plant variety. For example, a § 161 plant patent gives the holder the right to "exclude others from asexually reproducing the plant or selling or using the plant so reproduced." 35 U.S.C. § 163. The rights associated with a PVP certificate (*i.e.* giving the plant breeder the right to "exclude others from selling the variety, or offering it for sale, or reproducing it, or importing it, or exporting it, or using it in producing [as distinguished from developing] a hybrid or different variety therefrom," 7 U.S.C. § 2483(a)(1)) are broader, and extend to any plant or variety that is "essentially derived from" or "not clearly distinguishable from a protected variety," or "whose

[6] U.S. Patent No. 3,861,079 (issued Jan. 21, 1975).

production requires the repeated use of a protected variety," and to harvested material derived from such varieties. 7 U.S.C. § 2541(c). In other words, PPA and PVPA rights are limited in scope to the *specific plant varieties protected*; they do not give the holder any rights over other plants with the same or similar characteristics. In addition, a PVP certificate holder cannot restrict uses of the variety that fall within a series of express exemptions relating to saving seeds, research, transportation, and advertising. *See* 7 U.S.C. §§ 2543-45.

A utility patent, by contrast, confers a broader range of protection, and does so with reference to objectively and precisely defined attributes of the invention. Thus the claims of a utility patent will typically extend not only to the specific example (*i.e.* the plant) described in the specification, but also to other embodiments (plants) that share the defining characteristics of the invention.

For example, if a utility patent describes a plant cell line engineered to produce human antibodies with useful and novel functional properties, claims may be drawn (*i.e.* the patent rights may extend) not only to the plant cell itself, but also to a plant grown from the cell line, methods of making the plant, methods of using the plant to produce antibodies, the antibodies themselves, and if appropriate, the introduced genes that cause the cell line to exhibit its desirable functional properties.[7] Similarly, a utility patent that describes an herbicide-resistant plant could give the inventor rights not limited to the plant alone, but to the inventions that are manifested in any plant having the same characteristics that make the original plant herbicide-

[7] *See, e.g.*, U.S. Patent No. 6,040,498 (issued Mar. 21, 2000) (claiming duckweed plants modified to produce various proteins including antibodies, protein hormones, and tumor suppressors).

resistant.[8] In sum, in exchange for satisfying more stringent and demanding standards for patentability (*i.e.* novelty, usefulness, non-obviousness, and disclosure), utility patents grant exclusive rights to the inventor that are much broader than those associated with either § 161 plant patents or PVP certificates.

C. Utility Patents, § 161 Plant Patents, and PVP Certificates Are Complementary and Serve the Public Interest.

The agricultural biotechnology industry is thriving, thanks in large part to the inventive activity encouraged by the availability of utility patent protection as a complement to PPA and PVPA protection. Patents have issued on corn plants expressing *Bacillus thuringiensis* (*Bt*) insecticidal proteins;[9] herbicide-resistant crops, such as sugar beets containing the ROUNDUP READY™ gene;[10] sunflowers "conventionally" bred to contain relatively high levels of the more healthful unsaturated oleic acid;[11] bananas, tomatoes, and other fruit recombinantly modified to contain edible vaccines;[12] plants that produce nutritionally superior mixtures of dietary amino acids;[13] and maize with increased

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[8] *See, e.g.*, U.S. Patent No. 4,761,373 (issued Aug. 2, 1988) (claiming any maize plant expressing an altered acetohydroxyacid synthase enzyme, resulting in tolerance to exposure to certain chemical herbicides).

[9] *See* U.S. Patent No. 5,484,956 (issued Jan. 16, 1996).

[10] *See* U.S. Patent No. 6,204,436 (issued Mar. 20, 2001).

[11] *See* U.S. Patent No. 4,627,192 (issued Dec. 9, 1986).

[12] *See* U.S. Patent No. 5,861,277 (issued Jan. 19, 1999).

[13] *See, e.g.*, U.S. Patent No. 5,508,468 (issued Apr. 16, 1996).

water stress tolerance.[14] Though none of these inventions could have been envisioned a century ago, the incentives provided by utility patents spurred the creation of crops with the potential to increase the efficiency of agricultural production and to improve the health of many in this country and around the world.

Individually and in concert, the three intellectual property schemes applicable to plants promote the useful arts and facilitate commerce. They meet different commercial needs, demand compliance with substantively distinct requirements, and encourage different innovative activities—all for the benefit of the public.

For example, by protecting technological advances embodied in plants that cannot necessarily satisfy the more rigorous standards of the utility patent statute, the PPA and PVPA nevertheless provide a measure of enforceable commercial protection for every important new plant variety. Even when more than one statute might apply, the PPA and PVPA are effective *alternative* or *complementary* forms of legal protection to utility patents. Many plant growers and distributors, for example, may be better served by the lesser PPA or PVPA protections, because they come at a lower cost and with less effort than a utility patent.

If an inventor decides to pursue a utility patent rather than—or in addition to—a § 161 plant patent or a PVP certificate, he will have to supply a detailed description of "the manner of making and using" his plant-related invention, as uniquely required by 35 U.S.C. § 112. This requirement benefits the public by adding the contents of the patent's disclosure to the storehouse of scientific and technical knowledge—in this case, knowledge about how to make plants with the claimed characteristics and attributes.

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[14] *See* U.S. Patent No. 5,780,709 (issued July 14, 1998).

In contrast, the minimal description required for a PVP certificate or a § 161 plant patent cannot teach the public how to impart the desirable characteristics of the variety it concerns, such as expression of a disease resistance gene, into other varieties.

D. Concurrent Intellectual Property Protection in a Single Physical Article Does Not Suggest a Conflicting Statutory Scheme.

The suggestion that a unitary object, such as a single plant, may be protected by more than one form of intellectual property is not new to intellectual property law. As this Court[15] and other tribunals[16] have long recognized, there is not necessarily a one-to-one correspondence between a physical object and the intellectual property that it may embody. One could easily envision a patented disk drive storing copyrighted software, or a desktop computer having patented circuitry, ornamental features claimed in a design patent, and a control panel arranged in a recognizable configuration protected as trade dress.

Just as a single act of misappropriation—say, replicating a desktop computer or a plant—may infringe multiple and distinct intellectual property rights existing in that article, the creation of a single new article may give rise to more than one statutory entitlement to protection. This is

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[15] *Traffix Devices, Inc. v. Marketing Displays, Inc.*, 121 S. Ct. 1255, 1262 (2001) (patentable features and protected trade dress may in theory coexist in a single device if the elements of the trade dress are not functional).

[16] *See, e.g., In re Yardley*, 493 F.2d 1389, 1393-95 (C.C.P.A. 1974) (because ornamental design is statutory subject matter under both copyright and design patent statutes, author-inventor may secure rights under both schemes, citing *Mazer v. Stein*, 347 U.S. 201, 217 (1954)).

the case with plant innovations. A single disease-resistant soybean plant, for example, could simultaneously (1) *embody* the invention of inserting a resistance gene into the genome of a legume (such as a lentil or a soybean), for purposes of 35 U.S.C. § 101, and (2) *constitute* a new, distinct, uniform, and stable variety of soybean plant protectable under the PVPA.

Far from being in conflict, the utility patent regime operates in harmony with the PPA and PVPA. These statutes protect different innovations that Congress has determined that it is in the public interest to promote, and they afford different combinations of enforceable rights. Of course the scope of rights obtained concurrently under two distinct statutes will likely be broader than the rights conferred by either statute alone. But that accumulation of rights does not take away from the inventor any rights that he possesses by virtue of any single intellectual property instrument—neither statute compels him to do or refrain from doing anything that the other forbids. If the inventor has simultaneously produced a new plant variety that Congress protects under the PPA or PVPA, as well as an innovation that manifests itself in the plant and is sufficiently inventive to meet Congress's tests for utility patent protection, he is entitled to be protected by both of Congress's statutory schemes. There simply is no conflict between these distinct and complementary statutes.

II. This Court and Congress Have Made Clear That Plant Inventions May Be Protected by Utility Patents.

Neither this Court nor Congress has been troubled by the broad and flexible reach of the utility patent statute as it applies to plants. Congress wisely designed a utility patent statute that could accommodate scientific inventions that were unforeseeable at the time of its passage. This Court has understood and given force to Congress's flexible

design in decisions such as *Diamond v. Chakrabarty*, 447 U.S. 303 (1980). In the specific case of plant inventions, it should again read the utility patent statute broadly—particularly because Congress has repeatedly indicated that it is aware of, and even endorses, the complementary intellectual property systems applicable to plants inventions and plant varieties.

A. This Court Reads the Utility Patent Statute Broadly

Nothing in the language of 35 U.S.C. § 101 excludes plants from its coverage. To the contrary, § 101's expansive scope is quite clear on its face:

> Whoever invents or discovers *any new and useful* process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Id. (emphasis added). The issue in this case is *not* whether "*anything* under the sun that is made by man" is patentable subject matter under § 101. *Chakrabarty*, 447 U.S. at 309 (emphasis added). Instead, the question presented here is a much more specific one: whether plants resulting from inventive human activity are "manufactures" or compositions of matter within the meaning of § 101.

Indeed, the oft-quoted reference to "anything under the sun that is made by man"—cited and disparaged by Petitioner—is a red herring. The critical answer that this Court supplied in *Chakrabarty* was to the question of whether there was any confusion as to the scope of the term "manufacture" as used in § 101. As the Court held, the answer is an emphatic "no." The Court explained,

> In cases of statutory construction we begin, of course, with the language of the statute. And

> "unless otherwise defined, words will be interpreted as taking their ordinary, contemporary common meaning." We have also cautioned that courts "should not read into the patent laws limitations and conditions which the legislature has not expressed."
>
> Guided by these canons of construction, this Court has read the term "manufacture" in § 101 in accordance with its dictionary definition to mean "the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery." . . . In choosing such expansive terms as "manufacture" and "composition of matter," modified by the comprehensive "any," Congress plainly contemplated that the patent laws would be given wide scope.

Id. at 308 (citations omitted).

Thus, the *Chakrabarty* decision makes clear that § 101 must be interpreted to find that "new and useful" inventions embodied in plants and plant varieties are "manufactures" eligible for utility patents, as long as they are produced "from raw or prepared materials by giving these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery." *Id.* If they are, and they meet the other requirements of the statute (*i.e.* they are novel, useful, non-obvious, and fully described), they are entitled to full utility patent protection.

B. Congress Has Repeatedly Made Clear That It Is Aware of, and Endorses, the Issuance of Utility Patents for Plant Inventions

Congress has consistently demonstrated that it is aware of, and supports, the complementary regimes of utility patents, PPA, and PVPA protection. Indeed, an expansive interpretation of the term "manufacture" in 35 U.S.C. § 101, as mandated by *Chakrabarty*, is perfectly consistent with Congress's understanding of and support for the distinct forms of intellectual property protection made available for plants under U.S. law.

For over fifteen years, since the PTO's decision in *Ex parte Hibberd*, 227 U.S.P.Q. 443 (Bd. Pat. App. & Interf. 1985), which gave a green light to plant-related utility patents, Congress has been aware of the fact that multiple distinct forms of legal protection are available for intellectual property embodied in a plant. The parties in this appeal have extensively documented Congress's deliberations regarding the PPA and the PVPA, and BIO will not repeat that history here. BIO wishes to bring to the Court's attention, however, several examples of legislative history outside the context of the PPA's and PVPA's enactment that serve to illustrate Congress's awareness and endorsement of the complementary intellectual property regimes.

Having passed some 15 acts making substantive changes to the patent statutes since 1985,[17] including several

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[17] *See* American Inventors Protection Act of 1999, Pub. L. No. 106-113 § 4001 *et seq.*, 113 Stat. 1501 (1999); Economic Development Administration and Appalachian Regional Development Reform Act of 1998, Pub. L. No. 105-393, 112 Stat. 3596 (1998); Plant Patent Amendments Act of 1998, Pub. L. No. 105-289, 112 Stat. 2780 (1998); Omnibus Consolidated Appropriations Act of 1997, Pub. L. No. 104-208 § 616, 110 Stat. 3009 (1996); Biotechnological Process Patents Act, Pub. L. No. 104-41, 109 Stat. 351 (1995); Uruguay Round Agreements Act, Pub. L. No. 103-465 §§ 531-34, 108 Stat. 4809, 4982-90 (1994); North American Free Trade Agreement Implementation Act, Pub. L. No. 103-182 § 331, 107 Stat. 2057 (1994); Patent & Trademark Authorization Act of 1993, Pub. L. No. 103-179, 107 Stat. 2040 (1993); Patent and Plant Variety Protection Remedy Clarification Act, Pub. L. No. 102-560, 106 Stat. 4230 (1992); Patent & Trademark Authorization Act of 1991, Pub. L. No. 102-204, 105 Stat. 1636 (1991); Act to Authorize Appropriations for the PTO, Pub. L. No. 100-703, 102 Stat. 4674 (1988); Generic Animal Drug and Patent Term Restoration Act, Pub. L. No. 100-670, 102 Stat. 3971 (1988); Process Patents Amendment Act of 1988, Pub. L. No. 100-418 § 9001 *et seq.*, 102 Stat. 1107 (1988); Act to Amend the Patent Laws Implementing the Patent Cooperation Treaty, Pub. L. No. 99-616, 100 Stat. 3485 (1986); Federal Technology Transfer Act of 1986, Pub. L. No. 99-502, 100 Stat. 1785 (1986).

that specifically addressed the issue of patents for biotechnological inventions,[18] Congress has had ample opportunities to put a stop to the granting of utility patents to plants if it were in any way concerned about a conflict between utility patents and rights granted under the PPA and PVPA. Congress has never done so. To the contrary, the legislative history of a number of these amendments since *Hibberd* demonstrates Congress's affirmative understanding

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[18] For example, the Biotechnological Process Patents Act amended 35 U.S.C. § 103 to provide an option for an applicant to establish the non-obviousness of a use of a biotechnological product that was itself novel and non-obvious. *See* Pub. L. No. 104-41 § 1, 109 Stat. at 351. Section 4805 of the American Inventors Protection Act of 1999 directed the PTO to produce a study on the potential risks to the U.S. biotechnology industry arising from the practice of depositing biological materials in support of biotechnology patent applications. *See* Pub. L. No. 106-113 § 4805, 113 Stat. at 1501A-590.

and approval of the view that plant inventions are patentable subject matter under § 101.

For example, in 1990 Congress considered the Patent Competitiveness and Technological Innovation Act. The House Report on that bill included an extensive discussion of intellectual property rights in plants, including a summary of the PTO's decision in *Hibberd*, as well as *Ex parte Allen*, 2 U.S.P.Q. 2d 1425 (Bd. Pat. App. & Interf. 1987) (holding that § 101's scope extends to modified multicellular animals). *See* H.R. Rep. No. 960(I), 101st Cong., 2d Sess. (1990). The Report specifically noted the announcement of the Commissioner of Patents and Trademarks that the "PTO would examine applications on inventions relating to plant life." *Id.*(citing 1060 Off. Gaz. Pat. & Trademark Off. 4 (1985)). Clearly, the House was well aware that utility patents were being issued for plant-related inventions.

Likewise, the House Report on the Plant Variety Protection Act Amendments of 1994 specifically clarifies Congress's understanding that new plant varieties reproduced by seed are covered by multiple forms of protection:

> In the United States, *one* effective form of protecting new plant varieties that are reproduced by seed is by means of the Plant Variety Protection Act.

H.R. Rep. No. 699, 103rd Cong., 2d Sess. (1994), *reprinted in* 1994 U.S.C.C.A.N. 2423 (emphasis added). When introducing this legislation in the Senate, sponsor Senator Kerrey expanded on this point:

> Mr. President, Federal protection of intellectual property rights that arise from plant breeding is available in the United States *in three forms*: Plant patents, plant variety protection, and utility patents. . . . In recent years, so-called utility patents have been granted on living materials under the Patent and Trademark Act. Both asexually and sexually-reproduced plants which have been developed by traditional breeding, genetic engineering, tissue culture, and various other methods have received utility patents.

139 Cong. Rec. S10868 (Aug. 6, 1993) (emphasis added). *See also* Statement of Senator Kerrey on S. 1406, The Plant Variety Protection Act Amendments of 1993, Federal Document Clearing House Congressional Testimony (Sept. 20, 1993) ("Currently, federal protection of intellectual property rights that arise from plant breeding is available in the United States in three forms: plant patents, plant variety protection, and utility patents.").

In giving its "advice and consent" in 1998 to the 1991 Act of the International Convention for the Protection of New Varieties of Plants ("UPOV"), the Senate again confirmed this understanding. *See* 144 Cong. Rec. S7519-01 (July 6, 1998). Earlier Acts of the UPOV Convention generally prohibited signatories from providing "dual protection" (*i.e.* both patents and plant variety protections) for plant inventions. The United States advocated the removal of that prohibition from what became the 1991 Act, so that it would be clear that developers of plant technology in the United States could continue to obtain multiple forms of intellectual property protection—including utility patents. The transmittal letter for the 1991 Act from the President to the Senate includes an analysis of the obligations of the contracting parties that makes the following point:

> Article 2 simply states that each Contracting Party "shall grant and protect breeders' rights." In that respect, the 1991 Act is silent on the form of breeders' rights to be provided and *no longer contains the provisions of Article 2 of the 1978 Act prohibiting a member State from providing*

> *protection by way of patents* . . . for the same botanical genus or species.

Message from the President of the United States Transmitting the International Convention for the Protection of New Varieties of Plants of December 2, 1961, as Revised, Treaty Doc. 104-17, 104th Cong., 1st Sess. (May 10, 1995) (emphasis added). This analysis confirmed for Congress that the Convention was now consistent with the current practice in the United States of granting both utility patents and plant variety protection to sexually reproduced plants.

In addition, PTO representatives have been clear about the interaction of these plant-related regimes in their testimony before Congress. As early as 1987, the Assistant Commissioner for Patents confirmed that "[a]t the present time, parties [looking to protect plant innovations] have a choice of coming in under the general patent laws now, or going in under the Plant Variety Protection Act to cover their subject matter, and they can assess their relative merits for their type of situation under those systems." *Patents and the Constitution: Transgenic Animals, Hearings before the Subcommittee on Courts, Civil Liberties and the Administration of Justice of the House Committee on the Judiciary*, 100th Cong. 29 (June 11, 1987) (testimony of Rene Tegtmeyer).

Thus, Congress has clearly and repeatedly been advised, and has stated its understanding, that there are multiple forms of intellectual property for plants in the U.S. statutory scheme. Congress has had ample opportunities to modify this scheme, including through a number of acts specifically addressing biotechnology inventions. It has never elected to take any steps in that direction. Indeed, in those instances when Congress has addressed the co-existence of multiple systems of protection for plants, it not only has not expressed any concern, but has actually

acknowledged and endorsed the co-existing regimes. Given this context, the Court should continue, as it did in *Chakrabarty*, to read 35 U.S.C. § 101 exactly as broadly as it is stated and with the same understanding as to its breadth—in other words, to extend patent eligibility to "any" new, useful, and non-obvious manufacture, including one embodied in a plant.

CONCLUSION

For the foregoing reasons, *amicus curiae* the Biotechnology Industry Organization respectfully asks this Court to affirm the judgment of the Court of Appeals that seeds and seed-grown plants are patentable subject matter under 35 U.S.C. § 101 *et seq.*

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